CLAIMS :

We claim:

1. A process for the preparation and purification of protein(s) such as viral antigenic proteins, other recombinant therapeutic proteins characterized in that the purification is carried out by a novel technique termed as HIMAX technology which is as herein described and recovering the said protein(s).
2. The process as claimed in claim 1 wherein the said protein(s) is/are made to be expressed in the vectors like prokaryotic cell or eukaryotic cell like E.Coli, yeast, etc.
3. The process as claimed in the preceding claims wherein the said process and purification comprising-
   (a) the vector cells are subjected to lysis in the absence of a detergent to obtain a cell lysate;
   (b) subjecting the cell lysate of steps as to centrifugation ranging from 1000g to 10,000g;
   (c) obtaining a solid from step(b) by decantation wherein the said solid comprising the said proteins;
   (d) suspending the said solid in a buffer of pH 6 to 7.5 and optimally treating this with a detergent such as herein described to solubulize the minute impurities if any;
   (e) as a part of HIMAX technology, the said protein(s) is/are captured by the addition of divalent ionic salt having concentration ranging from 0.2% to 10% with counter ions of either phosphate, chloride and/or acetate solution to form an insoluble matrix;

(f) subjecting the said insoluble matrix for centrifugation optimally to form pellets;

(g) subjecting repeated desorptions process to release the bound antigen from insoluble matrix/pellets by using either Tris buffer of Ph 8.0 to 8.5 or Tris buffer with EDTA at Ph 7.0 to 8.0;

(h) finally recovering the said proteins through ultrafiltration, chromatography on colloidal silica, hydrophobic and or affinity chromatography, ion exchange, diafiltration, sterile filtration or a combination thereof.

4. The process as claimed in any of the preceding claims wherein the said protein is a viral antigen.

5. The process as claimed in claim 4 wherein inactivation of viral antigens is carried out by a known manner before subjecting to desorption (by chromatography) step.

6. The process as claimed in claims 1 to 3 wherein the said protein is other than viral antigen.

7. The process as claimed in claim 6 wherein inactivation step is avoided before desorption.

8. The process as claimed in the preceding claims wherein the chromotographically purified fractions containing the desired protein(s) are pooled for diafiltration and or for sterile filtration.

9. The process as claimed in the preceding claims wherein the divalent cations is preferably Zn, ca, Mg or a combination thereof.

10. The process as claimed in step (d) of claim 3 wherein the detergent is non-ionic detergent.

11. The process as claimed in step (d) of claim 3 wherein the detergent is not used.

12. The process as claimed in step (h) of claim 3 wherein ultra filtration is carried out using membrane filters of 100-300K molecular weight cut off.

13. The process as claimed in step (h) of claim 3 wherein the ion-exchange matrices is selected from anionic exchange resins such as sulphated cellulose/DEAE matrices.

14. The process as claimed in the preceding claims wherein the said proteins are highly purified without the loss of biological activity.

15. The process as claimed in the preceding claims wherein the contaminants like nucleic acid fragments etc., does not interfere/affect the said process of preparation and purification of the said proteins.

16. The process as claimed in any of the preceding claims wherein viral antigens, recombinant proteins, biotherapeutic proteins etc., are simultaneously prepared and purified.